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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,924	12/13/2006	Jon Bondebjerg	4614-0185PUS1	4359

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EXAMINER	
YOUNG, SHAWQUIA	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,924	BONDEBJERG ET AL.	
	Examiner	Art Unit	
	SHAWQUIA YOUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-11,13,15,20-23 and 36* is/are rejected.

7)☒ Claim(s) *4-8,12,14,16-19,24-26 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/05; 4/28/06; 2/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-37 are currently pending in the instant application. Applicants added new claims 36-37 in an amendment filed on April 11, 2008.

I. *Priority*

The instant application is a 371 of PCT/DK04/00421, filed on June 17, 2004 which claims benefit of 60/479,961, filed on June 19, 2003 and claims benefit of DENMARK PA200300905, filed on June 18, 2003.

II. *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on December 15, 2005, April 28,2006 and February 22, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election with traverse of the Group with the scope of products found in claim 36 in the reply filed on April 11, 2008 is acknowledged. Traversal is on the grounds that the restriction between the generic claims was improper.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict

applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

The Restriction Requirement detailed the reasons for restriction between the groups. Applicants claimed compound embraces various independent and distinct inventions. Different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The inventions are classified into classes 514, 544, 546, 548, 549, 564, etc. For example, R1 and R3 in formula I can form a C3-C7 heterocycloalkyl group (i.e., pyrrole, morpholine, piperidine, etc.). These compounds would be classified differently and would involve different search considerations. The pyrrole group is classified in class 548, the morpholine group is in class 544 and the piperidine is in class 546. These compounds would required different search considerations whereas when there is no heterocyclic group present then the compounds would be classified in class 564.

Further, each Class 514, 544, 546, 548, 549 and 564 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety.

Subject matter not encompassed by elected Group drawn to the scope of the products in claim 36 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions. Method claims 27-35 have been

withdrawn from consideration and will be rejoined when the product claims have been found allowable.

IV. *Rejections*

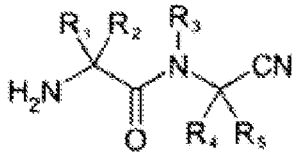
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9-11, 13, 15 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by *Altmann, et al.* (See RN 225122-44-1, CAPLUS). The instant invention



claims a product with the formula wherein R1 is C1-6 alkyl optionally substituted with a substituent selected from the group consisting of halogen, amino, hydroxyl, cyano and C1-3alkoxy; an unsubstituted or substituted C3-10 cycloalkyl group; an unsubstituted or substituted C1-6alkylaryl group; an unsubstituted or substituted C1-6 alkylheteroaryl group or an unsubstituted or substituted aryl group; R2 is hydrogen; R3 is hydrogen; R4 is C1-6 alkyl; an unsubstituted or substituted C1-6alkylaryl group; an unsubstituted or substituted C2-6 alkenylaryl group.; or

unsubstituted C1-6 alkylheteroaryl group and R5 is hydrogen; wherein a substituted group is substituted with one, two or three substituents as defined in claim 36.

The *Altmann, et al.* reference teaches nitrile compounds such as 2-amino-N-[(1S)-1-cyano-3-methylbutyl]-4-methyl-(2S)-pentanamide. This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,

2. the state of the prior art,

3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

Applicants are claiming a compound of formula I for use in medicine. See, for example, instant claims 20-23.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that cognitive disorders, for example, remain highly unpredictable. Enablement for the scope of a compound of formula I for use in treatment, prophylaxis and/or diagnosis for the various diseases listed in claim 23 is not present in the specification.

Furthermore, there is a vast range of causes for the problem and biochemical pathways that mediate cognitive disorders that affect the various nervous systems. There is no common mechanism by which all, or even most, of the listed diseases arise and one treatment cannot be used to all of the various diseases listed in claim 23.

For example, Applicants' claims are therefore drawn to a compound for use in the treatment, prophylaxis and/or diagnosis of Alzheimer's disease. It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early

stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease. (<URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html>.)

In addition, Layzer, Cecil Textbook of Medicine (article enclosed), states that "some degenerative diseases are difficult to classify because they involve multiple anatomic locations" (see page 2050). Alzheimer's disease has traditionally been very difficult or impossible to prevent or even to treat effectively with chemotherapeutic agents (*See* e.g., the Cecil Textbood of Medicine, 20th edition (1996), Vol. 2, page 1994).

There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the numerous diseases or disorders claimed herein. That a single class of compounds can

be used to treat or control all diseases embraced by the claims is an incredible finding for which Applicants have not provided supporting evidence. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating, controlling or preventing any or all conditions by administering the instant claimed compounds.

The breadth of the claims

The breadth of the claims is a compound for use in medicine.

The quantity of experimentation needed

The nature of the pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The level of the skill in the art

Even though the level of skill in the pharmaceutical art is very high, based on the unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

To overcome the rejection, applicants are suggested, for example, to cancel claims 20-23.

V. *Objections*

Dependent Claim Objections

Dependent Claims 2-26 and 37 are also objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

Claim Objection-Non Elected Subject Matter

Claims 1-26 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

VI. *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626